

REMARKS AND CONCLUSIONS

Claims Status

Claims 1-104 and 136-139 have been canceled. Claims 105-135 and 140 remain in the application. Claims 105-107 and 140 belong to the elected Group III. Applicants elected the species of an extract of black raspberry with the additionally added compound of ellagic acid, a derivative of gallic acid. Claims that read on the elected species are claims 105, 106, and new claim 140.

Claims 108-135 have been withdrawn as belonging to the restricted Group IV which Applicants submit should be rejoined as a single inventive concept and as dictated in MPEP §821.04 as discussed below.

Restriction Requirement

Notice of Applicants' Intent to Submit a Formal Petition for Review.

For the reasons given in Applicants' January 7, 2009 Amendment, it is respectfully submitted that the Office has not applied the correct standard and has not followed its own guidelines in restricting Groups III and IV without possibility of rejoinder.

The Office is reminded that Applicants have canceled the claims included in Groups I and II. Applicants are only asserting that Groups III and IV share a single technical feature and that these groups should be rejoined if the product claims of Group III are found allowable. The Office found Group III unrelated to Group IV because the product as claimed "can be used in a materially different process of using." (December 8, 2008 Restriction Requirement, page 2).

This application is the national stage of a PCT application submitted under 35 U.S.C. §371, and the correct standard is "unity of invention" and not 37 C.F.R §1.141-1.146. M.P.E.P. §1893.03(d). As argued previously, the technical relationship between Groups III and IV is the composition as in Claim 105. Group IV claims are directed to a method of using this composition, and as claimed in the independent claim 108, require all the limitations of the independent product claim 105. Even if the Office believes that the special technical feature of Claim 105 is not novel, the Office must consider rejoinder of the method of using claims if Claim 105 is subsequently found to be

allowable. Any nonelected process of making and/or using an allowable product should be considered for rejoinder. The examiner should notify applicants of potential rejoinder of non-elected process claims by placing form paragraph 8.21.04 at the end of any lack of unity determination made between a product and a process of making the product or between a product and a process of using the product." M.P.E.P. §1893.03(d).

It is respectfully submitted that the restriction requirement should be modified or withdrawn since as shown below the product claim 105 is novel over the prior art.

The Office is respectfully advised that, should the present restriction requirement be maintained, and rejoinder of the process of using claims not allowed if the product claims are subsequently found allowable, then it is the Applicants' intention to file a formal Petition to seek review of the restriction requirement.

The Section 102(e) Rejection

Claims 105-107 and 140. Claims 105-107 and 140 were rejected under 35 U.S.C. 102(e) as anticipated by King *et al.* (U.S. Patent No. 7,208,181), as evidenced by a website. The Office cites King *et al.* for teaching an aqueous extract from black raspberry including ellagic acid.

A claim is considered anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. 2131.

Claim 105 reads: "An anti-angiogenic composition, wherein said composition is more soluble in alcohol than in water; wherein said composition contains compounds with a molecular weight less than 2000 Daltons; wherein said composition comprises gallic acid or a derivative of gallic acid; wherein said composition is, or is substantially similar to, a composition that elutes from an aqueous extract from black raspberry fruit with about 51% to about 95% ethanol from a polystyrene resin column with a pore size of 46; wherein said composition inhibits angiogenesis; and wherein said composition has a chemical fingerprint on high performance liquid chromatography substantially as shown in Fig. 17. "

The claimed composition is different from the composition described by King *et al.* Applicants' composition was characterized by HPLC and the claimed extract must have a chemical fingerprint on HPLC substantially as shown in Fig. 17. King *et al.*'s extract would not have this fingerprint since the King *et al.* specifically described a different process of making their extract, explicitly discounted Applicant's method of extraction, and recognized that their extract could be further fractionated, but did not identify any fractionated extract.

King *et al.* describe a process using sucritical water extraction (SWE) where the water temperatures are above 100°C and the ambient pressure is greater than 1 atm to prevent the water from boiling. (King, Fig. 1). "Pressures are selected to eliminate the boiling tendency of the solvent, and will be typically in the range of 10-50 atm (10-50 bar). (Col. 3, lines 64-66). This allows "that SWE can be applied to the extraction and isolation of anthocyanins and other polyphenolic compounds without substantial degradation thereof as a result of exposure to heat." (Col. 4, lines 12-16) Moreover, King *et al.* recognize that the extract could be further purified by chromatography to "further fractionate the polyphenolic compounds." (Col. 4, lines 49-59).

In contrast, Applicants make their crude extract by initially boiling in water for about 120 min ([Specification, paragraph [0181]]), thus causing substantial degradation according to King *et al.* (Col. 4, lines 12-16). Although boiling is not part of the claim, Claim 105 requires the extract to have a chromatography fingerprint as in Fig. 17. King *et al.* support that the fingerprint would be different from a boiled versus a non-boiled extract.

In addition, the claimed extract in Claim 105 is further purified by eluting "from an aqueous extract from black raspberry fruit with about 51% to about 95% ethanol from a polystyrene resin column with a pore size of 46." (Claim 105). Applicants then show that elutions from this column using less than 51% ethanol are not the same composition, since the elutions were not as effective as RUO-95 in inhibiting angiogenesis. (Specification, paragraph [0183] and Figs. 15A and 15B). Moreover, the fingerprint of the crude extract (RUO-C) (about 39 major components) was shown by applicants to be different than the fingerprint of the claimed extract (only 13 major peaks) (RUO-95). (Specification, paragraph [0181] and [0185], and comparing Fig. 14

to Fig. 17). Claim 105 claims a composition as with “a chemical fingerprint on high performance liquid chromatography substantially as shown in Fig. 17.” Thus Applicants have shown that the composition as in Claim 105 is different than that from the crude extract without further purification on a polystyrene resin.

Since King *et al.* do not further purify their extract, their extract is different than that claimed in Claim 105, and the claim is not anticipated by King *et al.*

Moreover, the claims would not be obvious over King *et al.* The object of King *et al.* was to use SWE to make an extract high in anthocyanins using water as the principal solvent. King *et al.* only use “minor amounts (up to about 45% v/v)” of solvents other than water, including solvents such as ethanol, acetone, ethyl acetate, or methylene chloride. The use of ethanol was up to a level of 30% (v/v). (Col. 3, lines 37-49).

In contrast, Applicants are selecting the purified extracts based on their antiangiogenic activity. This selection, and these extracts, would not be obvious in light of King *et al.* It is respectfully submitted that this rejection should be withdrawn, and than Claims 105-107 and 140 be allowed.

Conclusion

Applicants respectfully submit that the composition claims of Group III are in condition for allowance, and that the method claims of Group IV should then be rejoined, and all claims subsequently allowed.

Respectfully submitted,



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